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APPLICATION NO. FILING DATE		FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
10/783,152 02/20/2004		02/20/2004	Rafail Zubok	532/7X2	7040		
51640	7590	09/19/2006		EXAM	EXAMINER		
SPINE N			PELLEGRIN	PELLEGRINO, BRIAN E			
	., DAVID, TH AVEN	et al. IUE WEST	ART UNIT	PAPER NUMBER			
	ELD, NJ		3738	3738			
				DATE MAILED: 09/19/200	DATE MAILED: 09/19/2006		

Please find below and/or attached an Office communication concerning this application or proceeding.

_		Applicati	on No.	Applicant(s)					
			52	ZUBOK ET AL.					
	Office Action Summary	Examine	r	Art Unit					
		Brian E. f	Pellegrino	3738					
Period fo	The MAILING DATE of this commun or Reply	nication appears on th	e cover sheet with the c	correspondence addres	is				
A SH WHIC - Exter after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR CHEVER IS LONGER, FROM THE Management of time may be available under the provisions SIX (6) MONTHS from the mailing date of this come period for reply is specified above, the maximum set to reply within the set or extended period for reply reply received by the Office later than three months bed patent term adjustment. See 37 CFR 1.704(b).	MAILING DATE OF THE SOFT OF TH	HIS COMMUNICATION rent, however, may a reply be tin will expire SIX (6) MONTHS from blication to become ABANDONE	N. nely filed the mailing date of this commu D (35 U.S.C. § 133).					
Status									
1)[\	Responsive to communication(s) file	ed on 20 February 20	004						
•	•	2b)⊠ This action is i							
,	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is								
٠,۵	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.								
Dispositi	ion of Claims								
	4)⊠ Claim(s) <u>1-17</u> is/are pending in the application.								
•	4a) Of the above claim(s) <u>13-15</u> is/are withdrawn from consideration.								
	Claim(s) is/are allowed.								
•	Claim(s) 1-12,16 and 17 is/are rejected.								
•	Claim(s) <u>1-12, 16 and 11</u> is/are rejected.  Claim(s) is/are objected to.								
-	Claim(s) are subject to restri	ction and/or election	requirement.						
الــا(٥	Claim(s) are subject to resur		oquii omom.		•				
Applicat	ion Papers								
, —	The specification is objected to by the								
10)[	The drawing(s) filed on is/are								
	Applicant may not request that any object	ection to the drawing(s)	be held in abeyance. Se	e 37 CFR 1.85(a).					
	Replacement drawing sheet(s) including								
11)	The oath or declaration is objected to	o by the Examiner. N	ote the attached Office	Action or form PTO-1	152.				
Priority (	under 35 U.S.C. § 119								
	Acknowledgment is made of a claim  ☐ All b)☐ Some * c)☐ None of:  1.☐ Certified copies of the priority			)-(d) or (f).					
	2. Certified copies of the priority			ion No.					
	Copies of the certified copies application from the Internation	of the priority docum	ents have been receive		ge				
* (	See the attached detailed Office acti	on for a list of the cer	tified copies not receive	ed.					
Attachmer	nt(s)								
	ce of References Cited (PTO-892)		4) Interview Summary						
2) Notice 3) Information	ce of Draftsperson's Patent Drawing Review (mation Disclosure Statement(s) (PTO/SB/08) or No(s)/Mail Date		Paper No(s)/Mail D 5) Notice of Informal I 6) Other:						
S Patent and	Frademark Office								

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#### **DETAILED ACTION**

### Election/Restrictions

This application contains claims directed to the following patentably distinct species:

Specie I: Figs. 7-9.

Species II: Figs. 10,11.

The species are independent or distinct because the two implant tools both operate differently and have different capabilities, for example the tool illustrated as Specie II allows for distraction of the vertebrae and the other tool allows to push the implant into the space where the prosthetic device is to be implanted.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, none are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

During a telephone conversation with Raymond Garguilo on 9/13/06 a provisional election was made without traverse to prosecute the invention of Specie II, claims 1-12,16,17. Affirmation of this election must be made by applicant in replying to this Office action. Claims 13-15 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected specie. Claim 13 recites a manipulation device, which is inserted into the plying device and can be seen in Fig. 9.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### Specification

The specification is objected to because reference character "5120" has been used to designate both "prong" and "leg" in paragraphs 48,49 respectively.

Appropriate correction is required.

# Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3,5,9,11, 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Marnay (WO 91/13598). Fig. 10 shows an instrument having a plying device with two distal ends 811,821 with two opposing fork-shaped extensions. Fig. 11 shows the instrument has a U-shaped member with a pair of laterally spaced tines 812,813 oriented perpendicular to base (811,821) that terminates from elongate section 820. It can also be seen (Fig. 11) that the fork-shaped extensions are oriented offset from the longitudinal axis of the plying device and interior sides face each other and are "adapted to" releasably grasp an intervertebral disc. It can also be construed that since the height of the base is greater than the fork-shaped extensions (Fig. 10) that the base forms a vertebral body stop. The fork-shaped extensions are fully capable of distracting an intervertebral space since the device is hinged (Fig. 10) and has at least two hinges (Fig.11). Fig. 1 shows an artificial intervertebral disc with upper and lower baseplates 110,120 with apertures to engage the fork-shaped extensions.

Claims 1-3,5,8-11,16 are rejected under 35 U.S.C. 102(b) as being anticipated by Keller (DE 3023942). Fig. 1 shows a vertebral prosthesis with upper and lower baseplates 3 that is placed in the vertebrae using a plying device having fork-shaped extensions 19 having a curved inner profile that engages the curved exterior section 1 of the prosthesis. Fig. 6 shows the plying device has at least two hinges.

Claims 1-3,5-10,16 are rejected under 35 U.S.C. 102(b) as being anticipated by Neumann (EP 1219266). Fig. 1 shows a vertebral prosthesis that can be construed to

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have upper and lower baseplates that is placed in the vertebrae and can be capable of distracting vertebrae by raising the telescoping portions of the prosthesis. Fig. 9 shows the fork-shaped extensions 27 offset from the longitudinal axis. Fig. 11 illustrates the fork-shaped extension having a base 26 and a pair of laterally spaced tines perpendicular to the base and slight notches in the interior between the upper and lower tines. Fig. 12 shows the upper portion of the base forms a forward ridge since it extends over the lower tines. Fig. 12 also shows the curved inner profile of the fork-shaped extension engaging the curved exterior section of the prosthesis.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4,17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marnay. Marnay is explained above. However, Marnay fails to disclose one of the tines aligned longitudinally with the elongate section of the instrument. Marnay does disclose a centrally located dome within the plates (Fig. 1) and teeth on the exterior of the plates apart from the dome. It would have been an obvious matter of design choice to modify the location of the tines, since applicant has not disclosed that using a tine that is longitudinally aligned with the elongate section of the fork-shaped extension or between spaced apart teeth provides any advantage, or solves a stated problem, or is used for

any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the location of tines taught by Marnay or the claimed aligned tine or centrally located tines in claim(s) 4,17 because both instruments perform the same function of holding a spinal implant and enabling a surgeon to implant the prosthesis.

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Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marnay in view of Michelson (6080155). Marnay is explained supra. However, Marnay does not disclose the extensions are detachable. Michelson shows (Fig. 2) detachable prongs from the instrumentation. Michelson also teaches (col. 21, lines 2-4,15-19) that the detachable extensions enable the surgeon to stabilize the implant and perform any other procedures at the implantation site by not having an elongate instrument extending from the patient. It would have been obvious to one of ordinary skill in the art to utilize a detachable forked extension as taught by Michelson and modify the instrumentation of Marnay such that the tool enables the surgeon to separate the handle from the extensions and thus prevents any inadvertent movement of the implant and allows the surgeon to perform any other necessary surgical measures.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-Th (9am-6:30pm) and alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700, AU 3738

BRIAN E. PELLEGRINO PRIMARY EXAMINER

Brian EPelleyris